JUL 2 1 2000

Lifestream INC
TECHNOLOGIES

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: **K000610**

Submitter Information (21 CFR 807.92(a)(1))

Submitter: Lifestream Technologies, Inc.
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Contact: Jackson B. Connolly
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Lifestream Technologies, Inc.
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Summary Date: June 30, 2000

Name of Device and Classification (21 CFR 807.92(a)(2))

Name (trade): Personal Cholesterol Monitor

Name (usual): total cholesterol test system

Classification: 21 CFR 862.1175, Class I, CHH

Identification of Legally Marketed Predicate Device(s) (21 CFR 807.92 (a)(3))

The Personal Cholesterol Monitor is substantially equivalent to the Cholestron Pro II Cholesterol Test (re-named the Lifestream Cholesterol Monitor). The Personal Cholesterol Monitor and Cholestron share the same intended use, methodology and technology, testing matrix, reportable range, and risk to the patient. The Personal Cholesterol Monitor is for over-the-counter use, and the Cholestron is for professional use.

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Description of Device (21 CFR 807.92 (a)(4))

The Personal Cholesterol Monitor system consists of a photometer with a display assembly keypad, and single-use, disposable reagent strips. Fingerstick whole blood is applied directly to the device, and cholesterol results are available in approximately three minutes.

Intended Use (21 CFR 807.92 (a)(5))

The Personal Cholesterol Monitor is an over-the-counter in vitro diagnostic device for the measurement of total cholesterol in fingerstick whole blood samples. Total cholesterol measurements aid in the detection of persons who may be at risk for coronary heart disease, and provide information for individuals who are attempting to lower their levels through diet and exercise, or who are under a physician's care with lipid lowering drugs.

Similarities to the Predicate(s) (21 CFR 807.92 (a)(6))

A summary table of the similarities and differences between the Personal Cholesterol Monitor and the predicate device (Cholestron) follows.

Similarities Between Resolution and Cholestron

CHARACTERISTIC	PERSONAL CHOLESTEROL MONITOR (K000610)	CHOLESTRON (K981345)
Intended Use	total cholesterol measurement to aid in the diagnosis and management of coronary heart disease	total cholesterol measurement to aid in the diagnosis and management of coronary heart disease
Analyte Measured	total cholesterol	total cholesterol
Methodology/Technology		
Strips:	Enzymatic reactions: cholesterol esterase and cholesterol oxidase (Trinder Reaction), individually packaged	Enzymatic reactions: cholesterol esterase and cholesterol oxidase (Trinder Reaction), individually packaged
Meter:	photometer	photometer
Result Display:	LCD direct readout	LCD direct readout
Calibration System:	Rom-key specific	Rom-key specific
Testing Matrix	fingerstick whole blood	fingerstick whole blood
Reportable Range	150-300 mg/dL	150-300 mg/dL
Risk to Patient	minimal, not a sole discriminate; total cholesterol results are interpreted along with medical histories and other biochemical markers	minimal, not a sole discriminate; total cholesterol results are interpreted along with medical histories and other biochemical markers
Safety Feature for Correct Reagent Strip Usage	includes external keypad that requires correct entry of reagent strip lot information	includes external keypad that requires correct entry of reagent strip lot information
User Interface	16-key	16-key
Battery Power	1 9-volt	1 9-volt
Required Maintenance	none, except cleaning	none, except cleaning
Data Downloading	Smart Card	Smart Card
Quality Control Recommendations	Labeling recommends Quality Control materials and procedures	Labeling recommends Quality Control materials and procedures

Differences Between Resolution and Cholestron

CHARACTERISTIC	PERSONAL CHOLESTEROL MONITOR (K000610)	CHOLESTRON K981345
Testing Environment	Over-the-counter	Professional use
Software Capabilities	Diagnostic + Memory + Display Conversion + Code # Correlation to Lot # (safety) *No cardiac risk assessment*	Diagnostic + Memory + Display Conversion + Code # Correlation to Lot # (safety) + Cardiac Risk Assessment
Customer Training	Required	Optional
Smart Card Capabilities	Storage and display of dated cholesterol result, and display of dated average of 6 prior results RS-232 port for download of test result	No such feature No such feature
Labeling	Targeted to the consumer market	Targeted to the professional market

Brief Discussion of Nonclinical Data (21 CFR 807.92(b)(1))

Laboratory tests were conducted to assess the effects of potential interferents on the cholesterol results; both biological and therapeutic compounds were evaluated. The results appear below.

INTERFERENCE TESTING WITH BIOLOGICAL COMPOUNDS

Potential Interferent	Level of Interference
Bilirubin	no interference in samples containing up to 10 mg/dL
Hemoglobin	hemolyzed samples (as would be seen in cases of excessive squeezing at the puncture site) should be avoided
High Hematocrit	cholesterol values were not affected when hematocrit levels ranged from 30% to 55%
Triglycerides	no interference in samples containing up to 400 mg/dL
Uric Acid	no interference in samples containing up to 9 mg/dL
Excessive Squeezing of Puncture Site	excessive squeezing and milking of the puncture site may produce erroneous results

Therapeutic Compounds

Specificity testing was performed with common therapeutic compounds. The following compounds, when present in pathological concentrations, were found to possibly alter cholesterol results.

Acetaminophen
Ascorbic Acid
Dopamine
Gentisic Acid
Methyldopa

Brief Discussion of Clinical Data (21 CFR 807.92 (b)(2)

Clinical studies were conducted with 413 lay users at three geographically-distinct US sites. Self-test results with the Personal Cholesterol Monitor were compared to both Abell-Kendall reference results (from venous sampling), and Monitor results obtained when testing was performed by trained personnel. Data were analyzed by least-squares linear regression statistics and biases at the 200 and 240 mg/dL NCEP cutpoints, and by classification categorizations (desirable, borderline high, and high cholesterol).

The Personal Cholesterol Monitor regression data demonstrated a negative bias of 2% at the 200 mg/dL cuptpoint, and a negative bias of 4.6% at the 240 mg/dL cutpoint. The professional Personal Cholesterol Monitor regression data demonstrated a positive bias of 2% at the 200 mg/dL cutpoint, and zero bias at the 240 mg/dL cutpoint.

The self-test Personal Cholesterol Monitor data demonstrated that 79% of results were correctly classified, and the professional Personal Cholesterol Monitor data demonstrated that 87% of the results were correctly classified, as compared to the Abell-Kendall reference method.

Performance Data - Conclusions (21 CFR 807.92 (b)(3))

Studies were conducted to evaluate Personal Cholesterol Monitor performance in the hands of the untrained, lay user. Subjects were able to use and interpret the Personal Cholesterol Monitor system with good accuracy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 21 2000

Mr. Jackson B. Connolly
Vice President, Product Development
Lifestream Technologies, Inc.
510 Clearwater Loop
Suite 101
Post Falls, Idaho 83854

Re: K000610
Trade Name: Resolution™ Cholesterol Monitor
Regulatory Class: I
Product Code: CHH
Dated: May 26, 2000
Received: May 30, 2000

Dear Mr. Connolly:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INTENDED USE

510(K) Number (if known): K000610

Device Name: Personal Cholesterol Monitor

Indications for Use:

The Personal Cholesterol Monitor is an over-the-counter in vitro diagnostic device for the measurement of total cholesterol in fingerstick whole blood samples. Total cholesterol measurements aid in the detection of persons who may be at risk for coronary heart disease, and provide information for individuals who are attempting to lower their levels through diet and exercise, or who are under a physician's care with lipid lowering drugs.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K000610

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE AS NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___ OR Over –the-Counter Use ✓
(Per 21 CFR 801.109)